

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|--------------------------------------|
| IN RE: PALBOCICLIB PATENT LITIGATION |) | MDL No. 19-2912 (CFC) |
| |) | |
| |) | |
| |) | |
| PFIZER INC., WARNER-LAMBERT |) | |
| COMPANY LLC, PF PRISM C.V., PFIZER |) | |
| MANUFACTURING HOLDINGS LLC, |) | |
| PFIZER PFE IRELAND |) | |
| PHARMACEUTICALS HOLDING 1 B.V., |) | |
| and PF PRISM IMB B.V. |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. 19-743 (CFC) (Consolidated) |
| |) | |
| AIZANT DRUG RESEARCH SOLUTIONS |) | |
| PVT. LTD., |) | |
| |) | |
| Defendant. |) | |
| |) | |
| PFIZER INC., WARNER-LAMBERT |) | |
| COMPANY LLC, PF PRISM C.V., PFIZER |) | |
| MANUFACTURING HOLDINGS LLC, |) | |
| PFIZER PFE IRELAND |) | |
| PHARMACEUTICALS HOLDING 1 B.V., |) | |
| and PF PRISM IMB B.V., |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. 19-1863 (CFC) |
| |) | |
| MYLAN PHARMACEUTICALS, INC. |) | |
| |) | |
| Defendant |) | |
| |) | |

STIPULATED PROTECTIVE ORDER

Disclosure and discovery in the above-caption matters (“Actions”) may involve the production of certain confidential, proprietary, or private documents, things, and information (including electronically stored information) in the possession, custody, or control of a party or a non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing, or other competitive information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or contain information involving privacy interests of individuals for which special protection from public disclosure and from use for any purpose other than prosecuting and defending the Actions may be warranted. Accordingly, Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; PF PRISM C.V.; Pfizer Manufacturing Holdings LLC; Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.; and PF PRISM IMB B.V. (collectively, “Plaintiffs” or “Pfizer”) and Defendants Aizant Drug Research Solutions Pvt. Ltd. (“Aizant”); Alembic Pharmaceuticals, Inc. and Alembic Pharmaceuticals Ltd. (collectively, “Alembic”); Apotex, Inc. and Apotex Corp. (collectively, “Apotex”); Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialties Ltd. (collectively, “Aurobindo”); Cipla USA Inc. and Cipla, Ltd. (collectively, “Cipla”); Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”); Hetero USA Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V, and Hetero Labs, Ltd. (collectively, “Hetero”); Mylan Pharmaceuticals Inc. (“Mylan”); Natco Pharma Inc. and Natco Pharma, Ltd. (collectively, “Natco”); Qilu Pharma, Inc. and Qilu Pharmaceutical Co., Ltd. (collectively, “Qilu”); Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE (collectively, “Sun”); Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (collectively, “Teva”); and Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide

DMCC, and Cadila Healthcare Ltd. (collectively, “Zydus”) have in good faith conferred and hereby stipulate to the entry of the following Protective Order in the Actions:

1. **Scope of Protective Order.** This Protective Order shall apply to all information, documents and things produced or within the scope of discovery in these Actions, including, without limitation, all testimony adduced at depositions, documents or things produced in response to requests for the production of documents and things, answers to interrogatories, responses to requests for admission and all other discovery taken pursuant to the Federal Rules of Civil Procedure, as well as hearing or trial transcripts, matters in evidence, and any other information furnished, directly or indirectly, by or on behalf of any party to this Action or any Third Party to the extent such material is designated “Confidential Information” in accordance with ¶ 2 of this Protective Order. This Protective Order shall also govern any designated record of information produced in these Actions pursuant to required disclosures under any procedural rule or District of Delaware Local Rule, and any supplementary disclosures thereto.

2. **Definitions.**

- a. “Producing Party” means a party or Third Party producing Confidential Information under this Protective Order.
- b. “Receiving Party” means a party or Third Party receiving Confidential Information under this Protective Order.
- c. “Confidential Information” means all information, in any form, that constitutes a “trade secret or other confidential research, development or commercial information” within the meaning of Fed. R. Civ. P. 26(c)(1) and includes, without limitation, all information that is not generally known to public or to competitors and that relates to product research, product development, product manufacturing, financial performance (whether

historical or future), marketing, sources of supply, business relationship with third parties, market analysis, or strategic planning.

d. “Third Party” or “Third Parties” means any person or entity who is not a named party in these Actions.

3. **Third Parties Under the Protective Order.** If a Third Party provides discovery to any party in connection with these Actions, and if the Third Party so elects, then the provisions of this Protective Order shall apply to such discovery, and the parties will treat all information that is produced by such Third Party in accordance with the terms of this Protective Order to the extent it is designated as Confidential. Under such circumstances, the Third Party shall have the same rights and obligations under this Protective Order as held by the parties to these Actions. Because Third Parties may be requested to produce documents containing information that a party considers Confidential Information, at the request of any party all documents produced by a Third Party in this action shall be treated as if designated Confidential hereunder for a period of seven days after production in order to allow the parties time to review the documents and make any appropriate designations hereunder.

4. **Designation.** Each party shall have the right to designate as “Confidential” any information that is Confidential Information as defined in paragraph 2(c), in accordance with the terms of this Protective Order. The designation of information as “Confidential” by the Producing Party constitutes a representation of that party that it reasonably and in good faith believes that the designated material constitutes Confidential Information. To the extent that material is designated Confidential, such material shall only be revealed to or used by limited categories of individuals, as provided for herein, and shall not be communicated in any manner, either directly or indirectly, to any person or entity except as provided herein. Any copies of

such material, abstracts, summaries, or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed Confidential, and the same terms regarding confidentiality of these materials shall apply as apply to the originals. The procedures for designating materials as Confidential are as follows:

a. **Designation of Documents and Things.** The parties and any Third Parties may designate as “Confidential” a document or thing that constitutes or contains Confidential Information by labeling or marking each page of that document with the legend “**CONFIDENTIAL**,” or by otherwise marking or designating in writing the materials as Confidential and subject to the Protective Order at the time such document or thing is produced to the Receiving Party. Anything that cannot be so marked shall be designated Confidential by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. Each page of each document and each thing produced pursuant to discovery in this Action shall also bear a unique identifying number.

Documents and things produced without a legend designating the material Confidential shall not be subject to this Protective Order unless otherwise agreed by the parties, ordered by the Court, or designated Confidential in accordance with the provision of paragraph 9 of this Protective Order (addressing inadvertent production). Inspection of documents or things by any party shall be conducted only by persons eligible to receive Confidential Information under this Protective Order. Such persons shall treat all information obtained during or from any inspection as though it were designated Confidential until such time as copies of documents or things from the inspection are produced, and, thereafter, such produced documents and things shall be treated in accordance with any confidentiality designation appearing on the document or thing at the time of its production.

A Producing Party may redact Confidential Information in a document or thing if that information is not relevant to the subject of this litigation or is subject to the attorney-client privilege or attorney work product protections. Any such redaction, regardless of size, shall be clearly labeled. This paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information, in accordance with paragraph 26 below. All documents redacted based on attorney-client privilege or work-product immunity shall be listed on a privilege log in accordance with Federal Rule of Civil Procedure 26(b)(5) and exchanged at a mutually agreeable date and time.

b. **Designation of Interrogatories, Requests for Admission and Written Testimony.** Any response to written interrogatories or requests for admission, or any testimony adduced at a deposition upon written questions (or any portion of any of the foregoing) that constitutes or contains Confidential Information, may be designated "Confidential" by the party providing the response or testimony as follows: (i) the specific pages or portions of pages containing Confidential Information shall be marked with the legend "**CONFIDENTIAL**", and (ii) the first page of that document near the caption shall be marked with the legend "**CONFIDENTIAL.**" Responses or testimony served without these legends shall not be treated as Confidential subject to this Protective Order unless otherwise agreed by the parties or ordered by the Court, or designated Confidential in accordance with the provisions of paragraph 9 of this Protective Order (addressing inadvertent production).

c. **Designation of Deposition Transcripts.** Deposition transcripts containing Confidential Information may be designated Confidential in accordance with this Protective Order either (1) on the record during the deposition, or (2) by providing written notice within 60 days of the date on which the deposition occurred.

All deposition transcripts not previously designated Confidential during the deposition shall be treated as Confidential under this Order for a period of 60 days from the date on which the deposition occurred, unless otherwise agreed to by the parties. After 60 days, deposition transcripts shall no longer be treated as Confidential unless one of the parties participating in the deposition has designated all or a portion of the testimony Confidential, or as otherwise agreed to by the parties. The parties agree to mark at least the first page of all copies of deposition transcripts that contain testimony, or that append exhibits, designated as Confidential with the legend “**CONFIDENTIAL**,” and to provide each other notice of which portions of the deposition transcript contain Confidential Information. This paragraph does not limit any party’s right to challenge any presumptive designation or preclude a Producing Party from designating testimony or transcripts as Confidential Information.

d. **Designation of Hearing Testimony or Argument.** With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of Confidential Information, counsel may designate on the record prior to such disclosure that the disclosure shall be deemed Confidential under the terms of this Protective Order. Whenever matter designated Confidential is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

5. **Limitations on Attendance at Depositions.** Counsel for a Producing Party may request that all persons other than those individuals expressly permitted access to Confidential Information under this Protective Order leave the deposition room during the portion of the deposition that inquires about or discloses subject matter that counsel for the Producing Party

believes to constitute Confidential Information. If individuals other than those specified in the previous sentence fail to leave the deposition room during any portion of the deposition that inquires about or discloses what counsel for the Producing Party believes to constitute Confidential Information, counsel for the Producing Party may seek relief from the appropriate Court and, pending resolution of its request for relief, instruct the witness not to answer questions relating to, or limit disclosure of, the Confidential Information at issue.

6. **Limitations on Attendance at Hearings or Trial.** Counsel shall confer with each other and with the Court regarding procedures to protect the confidentiality of any material marked, labeled, or otherwise designated Confidential that a party or any of its witnesses may use, refer to, disclose, or admit into evidence during trial or any hearing in this Action. Unless the Court orders otherwise, attendance at a hearing or at a trial session in this Action at which material designated Confidential will be used or disclosed shall be limited for the time period during which Confidential Information will be used or disclosed to individuals entitled to have access to such materials under the terms of this Protective Order.

7. **Use and Disclosure of Designated Information.** Subject to the limitations and restrictions of this Protective Order and any further order regarding confidentiality that the Court may enter, material marked, labeled, or otherwise designated Confidential as described in this Protective Order may be used to prepare for and conduct discovery, to prepare for trial, and to support or oppose any motion or other filing in these Actions, and may be used in testimony at trial, offered into evidence at trial and/or hearings on motions subject to such procedures mandated by the Court. Nothing herein shall be construed to affect in any way the admissibility of any document, testimony or other evidence at trial.

Material designated Confidential, and all information derived therefrom, shall be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the Receiving Parties to any party or person not entitled under this Protective Order to have access to such material, and shall not be used by the Receiving Parties for any purpose other than in connection with these Actions, including without limitation for any research, development, manufacture, patent prosecution, financial, commercial, marketing, regulatory, business, or other competitive purpose (except for settlement of the above-captioned case). Absent written consent of the Producing Parties or further order of this Court, all persons receiving information designated Confidential are expressly prohibited from using or disclosing such information in connection with any practice before or communication with the United States Patent and Trademark Office or the Patent Trial and Appeal Board, with the FDA (including Citizen Petitions), the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction, and are expressly prohibited from disclosing such information in connection with any civil action other than the above-captioned Actions.

8. **Storage of Designated Information.** The recipient of any information designated as Confidential shall maintain such information in a secure and safe area and shall exercise the same standard of due and proper care with respect to the storage, custody, use and/or dissemination of such information as is exercised by the recipient with respect to his/her/its own proprietary information.

9. **Inadvertent Production of Confidential Information.** If a party inadvertently produces or provides discovery of any Confidential Information without labeling or marking it as provided in this Protective Order, the Producing Party may give written notice to the Receiving Party or parties, within ten business days after becoming aware of the inadvertent production,

that the information should be treated as Confidential in accordance with the provisions of this Protective Order. The Producing Party will provide copies of the properly marked information (e.g., documents, discovery responses, transcripts, things, and/or all other information within the scope of this Protective Order). Upon receipt of such notice and properly marked information, the Receiving Party or parties shall return or destroy said unmarked or incorrectly marked information to the extent practicable and not retain copies thereof, and shall undertake a best effort to correct any disclosure of such information contrary to the redesignation. Prior to receipt of such notice, disclosure of such documents, things, information, responses and testimony to persons not authorized to receive Confidential Information shall not be deemed a violation of this Protective Order.

10. **Limitations on Advice to Clients.** It is understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated Confidential Information received by the party, provided that such rendering of advice and opinions shall not reveal the content of Confidential information, other than in summary form, except by prior written agreement with counsel for the Producing Party or as otherwise set forth in this Protective Order.

11. **Inadvertent Production of Privileged or Work Product Information.** Notwithstanding anything to the contrary in Fed. R. Civ. P. 26(b)(5)(B) or in any other provision of this Protective Order, the inadvertent production or disclosure of any document or tangible thing (including information) that is subject to a claim of attorney-client privilege or work-product immunity, or other privilege or immunity, shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claims of attorney-client privilege, work-product immunity, or other privilege or immunity. In such an event, the Producing Party shall send to

each Receiving Party a written request for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after becoming aware of such inadvertent or mistaken production. Within five business days of receiving a written request to do so from the Producing Party, the Receiving Party shall (a) return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work-product immunity, or other privilege or immunity, and were inadvertently or mistakenly produced and (b) destroy any copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information, including any electronic records thereof. The Receiving Party shall not utilize the information contained in the inadvertently produced documents or things for any purpose, or disseminate or transmit such information, after receiving written notice that it is subject to a claim of attorney-client privilege or work-product immunity.

12. If the Receiving Party wishes to contest that any such document or thing is protected from disclosure by the attorney-client privilege, work product immunity or other privilege or immunity from discovery, it shall so notify the Producing Party in writing when the document or thing is returned to the Producing Party (“Notice of Designation”).

13. Within five days after receiving a Notice of Designation, the Producing Party shall provide to the Receiving Party for each document or thing a description of the basis for the claim of privilege or immunity.

14. Within five days after receiving such description, the Receiving Party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the procedures set forth in the Court’s Scheduling

Order for resolution of discovery disputes. The party claiming the privilege or immunity shall have the burden of proving that such privilege or immunity exists.

15. With respect to documents and things subsequently generated by a Receiving Party, which documents and things contain information derived from such inadvertently produced documents and things, if the Receiving Party does not notify the Producing Party that the Receiving Party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the Receiving Party to the privileged status of the inadvertent production, the Receiving Party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

16. If, in a deposition, hearing, or other proceeding the party who made the inadvertent production or disclosure makes a request on or off the record for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after recognizing that the information has been produced or disclosed, all copies of the inadvertently produced or disclosed document or thing present at the deposition, hearing, or other proceeding shall immediately be sequestered and there shall be no further use of the inadvertently produced or disclosed document or thing. For the avoidance of any dispute, the marking of an inadvertently produced or disclosed document or thing as an exhibit at deposition, hearing, or other proceeding has no bearing on the timeliness of the request for return.

17. The procedures set forth in this paragraphs 12–16 for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney-client privilege, the work product immunity, or any other privilege or immunity.

18. **Access to and Disclosure of Confidential Information.** Every person to whom Confidential Information is to be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part shall first be advised that the material or information is being disclosed pursuant to the terms of this Protective Order and provided a copy of this Protective Order. Access to and disclosure of material marked, labeled, or otherwise designated Confidential as described in this Protective Order shall be made only to the following individuals:

a. Outside trial counsel or outside attorneys of record for the parties, including, but not limited to, such attorneys' partners, associates, staff and contract attorneys, and their authorized secretarial, paralegal, clerical, and legal-assistant staff whose duties and responsibilities require access to material designated Confidential.

b. Three in-house legal or intellectual property personnel for each party, or any parent or subsidiary entity of each party, as identified in Exhibit B,¹ who are actively responsible for either (a) directing the management and conduct of these Actions or (b) providing a party with legal advice with respect to these Actions, provided that the in-house designee first agree to be bound by the terms of this Protective Order by executing a copy of the attached Exhibit A. A party designating an individual under this paragraph represents that such designees do not, and will not for a period of one year following the final disposition of these Actions, have competitive decision-making authority for product marketing or business strategy (such as pricing and product design) relating to Ibrance® or any product containing palbociclib as its active ingredient. Notwithstanding the foregoing provisions, in-house designees shall be

¹ Exhibit B will be submitted within three business days after the day on which this Protective Order is entered by the Court.

permitted to advise their clients regarding legal strategy and the pending Actions; provided, however, that Confidential Information is not thereby disclosed.

c. Outside consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who first agree to be bound by the terms of this Protective Order by executing a copy of the attached Exhibit A, in accordance with paragraph 19, and who are not objected to pursuant to paragraph 20.

d. The Court before which these Actions are pending and their authorized staff.

e. Court reporters, videographers, and their respective staffs employed in connection with this action.

f. Any interpreter or translation service retained to assist outside counsel of record, and any typist or transcriber used thereby, who either first executes a copy of the Confidentiality Undertaking attached as Exhibit A or has made suitable arrangements with the party that has retained such an individual to preserve the confidentiality of the Confidential Information.

g. Non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, other litigation support personnel (e.g., graphic designers and animators, database entry personnel), and other third-party vendors, subject to the limitations of paragraph 21; and

h. Any other person as to whom the parties agree in writing.

[Defendants' Proposal: Subject to paragraph 7 and/or further order of the Court, Plaintiffs shall not disclose any material designated Confidential by a defendant in one of the Actions to a defendant in another Action absent the consent of the Producing Party.]

[Plaintiffs' Proposal: No party shall disclose any material designated Confidential by a Producing Party to another party without the consent of the Producing Party or by order of the Court, provided however, that any party shall be permitted to disclose in any trial, hearing, pleading, discovery response, deposition, or expert report that is properly designated as "Confidential" pursuant to this Order any material designated Confidential by any Producing Party. Notwithstanding anything in the Paragraph, no party shall disclose to a fact witness of one party, during his or her deposition, any material designated Confidential by another party.]

The individuals specified in paragraphs 18(a) – 18(b) who have received access to information designated Confidential by any party other than his or her client/employer shall not thereafter prosecute, supervise, or materially assist in the prosecution of any patent application (including both foreign and U.S.) that covers palbociclib (including without limitation compositions, methods, distribution methods, uses, or processes) for the length of these Actions plus 1 year after a final, non-appealable judgment in the last of these Actions to conclude. For the avoidance of doubt, "prosecution" includes directly or indirectly drafting, amending, advising, or otherwise affecting the scope of the patents-in-suit, a continuation, a divisional, a continuation-in-part, a reissue patent, or a patent application that covers palbociclib, including through the use of any post-grant proceedings such as *Inter Partes* Review, *Ex Parte* Reexamination, Covered Business Method Review, or related appeals that involve "prosecution" as set forth above. Notwithstanding the foregoing, nothing herein shall prohibit an individual from participating, supervising, or assisting with (1) the practice before or communication with the United States Patent and Trademark Office with respect to an *Inter Partes* Review, post grant review, or reissue or reexamination proceeding relating to palbociclib, or (2) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court

related to palbociclib, so long as that individual does not participate in any claim amendments. Further, such individuals specified in paragraphs 18(a) – 18(b) shall not directly participate in or advise any FDA correspondence, including Citizen Petitions, relating to pharmaceutical products containing palbociclib for the length of this Action plus 1 year after the final, non-appealable judgment in this Action, except where such work is updating the FDA on the status of this Action, responding to an inquiry from the FDA regarding the receiving party's own NDA or ANDA at issue in these Actions, or is directed toward obtaining or maintaining approval or regulatory exclusivities of the receiving party's own NDA or ANDA at issue in these Actions, provided that such individuals shall not disclose the Confidential Information of another party in connection with such work.

19. **Identification of Experts and Consultants.** If any party desires to disclose information designated Confidential (other than its own Confidential Information) to any expert or consultant pursuant to paragraph 18 of this Protective Order, it must first identify in writing (which can be by email) to the attorneys for the Producing Party each such expert or consultant. The identification of an expert or consultant pursuant to this paragraph shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae, any prior or current employments or consultancies for any party or other company in the pharmaceutical industry within the last five years that is in any way related to the research, synthesis, or development of any kinase inhibitor (except those engagements that are protected from disclosure pursuant to Fed. R. Civ. P. 26 or where the fact of the engagement itself is protected from disclosure by a confidentiality agreement), including a list of the cases in which the expert or consultant has testified at deposition, at a hearing, or at trial within the last 4 years, and an executed copy of the Confidentiality Undertaking attached hereto as Exhibit A.

20. **Objecting to Disclosure of Confidential Information to Experts and Consultants.** Counsel for the party providing discovery may, within the seven calendar day period, serve a notice of objection if a reasonable basis for such objection exists. If the notice is served, the Confidential Information will not be disclosed to such outside consultant. Within seven calendar days after service of the objection, if the parties are unable to reach any agreement over the disclosure of Confidential Information to the expert or consultant, counsel for the objecting party may subsequently move the Court for an order denying disclosure of any Confidential Information to the outside expert or consultant as to which a notice of objection has been served, in accordance with the procedures set forth in the Court's Scheduling Order for resolution of discovery disputes. If the objecting party files this motion, the Confidential Information shall not be disclosed to the outside expert or consultant until the Court rules or the parties agree that such disclosure may be made. Failure to file such a motion within the seven calendar day period shall operate as a waiver of this objection, unless the parties agree in writing to extend this deadline while meeting and conferring regarding the objection.

21. **Third Party Vendors.** Counsel may use the services of Third Party Vendors to provide services such as document review, electronic discovery support, computerized legal support, and management services for the purpose of encoding, loading into a computer and storing and maintaining for information control and retrieval purposes, transcripts of depositions, hearing, trials, pleadings, exhibits marked by any party, briefs and accompanying affidavits and appendices, documents produced by any party, or a party's own attorney work product, all of which may contain Confidential Information. Counsel desiring to disclose Confidential Information to a Third Party Vendor for the purposes of this paragraph shall first obtain a signed Confidentiality Undertaking on the form attached as Exhibit A, from a representative of the

vendor who may receive access to such material unless the Third Party Vendor is already subject to a general confidentiality obligation to such counsel. Counsel retaining the vendor shall retain the original of each such signed Confidentiality Undertaking. Service of the Undertaking shall not be required.

a. Third Party Vendors shall return to the party's counsel or confirm destruction of all copies of transcripts or other documents containing Confidential Information within 30 days of the conclusion of the last of these Actions to conclude, including any Appeals.

22. **Disclosure to Other Individuals.** Disclosure of Confidential Information may be made to individuals not identified in paragraph 18, above, only as follows:

a. Confidential Information may be disclosed to any person not otherwise identified in paragraph 18 above as agreed in writing by the party that designated such information Confidential.

b. Any party may move the Court for an Order that a person not identified in paragraph 18 above be given access to Confidential Information after first signing an Undertaking in the form of Exhibit A attached hereto. Counsel for the moving party shall retain the original of each such signed Undertaking. Service of the Undertaking shall not be required.

c. Confidential Information of a Producing Party may also be disclosed to and/or used to examine, at deposition and at trial (or other court hearing): (i) an individual who either prepared, received or reviewed the Confidential Information prior to filing of this Action or who previously had access to or knowledge of the Confidential Information, as demonstrated on the face of the Confidential Information itself or by foundation testimony elicited during a deposition or at trial; (ii) a currently employed officer, employee or expert of a Producing Party,

and/or; (iii) a witness designated for the Producing Party under Federal Rule 30(b)(6) concerning any topic to which the Confidential Information is relevant.

23. **Confidentiality of Party's Own Documents.** A party may disclose or use in any manner or for any purpose, any information or documents from that party's own files that the party itself has designated Confidential.

24. **Inadvertent Disclosure.** If Confidential Information is disclosed or comes into the possession of any person not authorized to receive such information under this Protective Order, the party responsible for the disclosure shall: (a) within five business days of becoming aware of such disclosure inform the designating party of all pertinent facts relating to such disclosure, including the identity of the person to whom the inadvertent disclosure was made; (b) use its best efforts to obtain the prompt return of the original and all copies of any such Confidential Information, and to bind such unauthorized person or party to the terms of this Protective Order; (c) within three business days of becoming aware of such disclosure, inform such unauthorized person or party of all provisions of this Protective Order; and (d) request such unauthorized person or party to sign the Confidentiality Undertaking in the form attached hereto as Exhibit A. The executed Confidentiality Undertaking shall be served upon counsel of record for the Producing Party within five business days of its execution by the person or party to whom Confidential Information was disclosed. The requirements set forth in this paragraph shall not prevent the Producing Party from applying to the Court for further or additional relief.

25. **Filing Under Seal.** Any information designated Confidential Information, if filed with the Court in connection with this Action, shall be filed under seal in accordance with the Local Rules or practice of the court in which the information is filed and shall be marked in the caption that the material is being filed under seal by adding the marking "**CONFIDENTIAL –**

FILED UNDER SEAL” below each case number appearing in the caption. In addition, any document that is to be filed with the Court and that contains or discloses Confidential Information shall be marked “**CONFIDENTIAL – FILED UNDER SEAL**” on its cover page. Material designated Confidential and filed under seal shall be maintained in such manner as provided for by the Court. However, the burden of proving that such document should be sealed shall at all times remain on the party that designated the document Confidential.

26. **Challenging Designations.** The acceptance or receipt by any party of material designated Confidential shall not constitute an admission or concession, or permit an inference that such material is, in fact, Confidential. Any Receiving Party may at any time request that the designating party cancel or modify the confidentiality designation with respect to any document, object, or information. Such request shall be made to counsel for the designating party in writing, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential or not Confidential, and the reasons supporting its contention. If the designating party does not agree to remove the Confidential designation within ten business days after receipt of such a request, then the party contending that such documents or material are not confidential may request by motion that the Court remove such material from the restrictions of this Protective Order in accordance with the procedures set forth in the Court’s Scheduling Order for resolution of discovery disputes. On such a motion, the party asserting confidentiality shall have the burden of proving that the material designated Confidential warrants protection under this Protective Order.

27. **No Expansion of Scope of Discovery.** Nothing in this Protective Order shall be construed to be an implied admission or to affect or govern the scope of discovery in this Action, or to preclude any party from moving the Court for a further order pursuant to Fed. R. Civ. P.

26(c), or any other provision of the Federal Rules of Civil Procedure. Nothing contained in this Protective Order shall be construed to require production or disclosure of any Confidential Information deemed by counsel for the party possessing such material to be protected from disclosure by the attorney-client privilege or the attorney work-product immunity, or any other privilege or immunity, so long as the withheld materials are identified in the manner required by the Federal Rules of Civil Procedure by the Producing Party. However, this Protective Order shall not prevent the parties from agreeing that certain categories of documents need not be identified, nor shall it prevent one or more parties from seeking relief from the Court if, e.g., identification of individual documents would be unduly burdensome. This Protective Order shall not preclude any party from moving the Court for an order compelling production or disclosure of such material in accordance with the procedures set forth in the Court's Scheduling Order for resolution of discovery disputes.

28. **New Parties to This Action.** In the event additional parties join or are joined in any of these Actions, they shall not have access to information designated Confidential by any other party until (a) the newly joined party or its counsel has executed and, at the request of any party, filed with the Court, its agreement to be fully bound by this Protective Order, or until (b) an alternative protective order is agreed to by all parties and entered by the Court.

29. **Miscellaneous.** This Protective Order shall not be construed to prevent any of the parties, or any Third Party, from applying to the Court for relief or further or additional protective orders, or from agreeing between or among themselves to modifications of this Protective Order, subject to the approval of the Court. The Protective Order shall not preclude the parties from enforcing their rights against any Third Party not associated with the Actions who is believed to be violating their rights.

30. **Other Proceedings.** By entering into this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

31. **Publicly Available Information.** This Protective Order shall not apply to any information of the parties which: (a) the producing or designating party or parties agree(s) should not be designated as Confidential; (b) the producing or designating party or parties agree(s), or the Court rules, is already public knowledge; (c) the producing or designating party or parties agree(s), or the Court rules, has become public knowledge other than as a result of disclosure by the Receiving Party, its employees, or agents in violation of this Protective Order; or (d) the producing or designating party or parties agree(s), or the Court rules, has come or shall come into the Receiving Party's legitimate knowledge or possession independently of the Producing Party under conditions such that its use and/or public disclosure by the Receiving Party would not violate any obligation to a party to any of these Actions. The restrictions and obligations set forth in this Protective Order shall not prohibit discussion of any material designated Confidential with any person who already has or obtains legitimate possession thereof.

32. **Survival of Obligations under Protective Order.** With respect to any information designated Confidential under this Protective Order, the rights and obligations under this Protective Order shall survive the final termination of these Actions to the extent the information in such material is not or does not become known to the public and continues to be

binding upon all persons to whom Confidential Information is disclosed hereunder. Upon final termination of this Action, the outside counsel of record for each party may retain (a) one copy of all deposition transcripts and exhibits thereto, (b) one copy of all trial transcripts and trial exhibits, (c) one copy of all pleadings and exhibits thereto, (d) one copy of all correspondence and exhibits thereto, (e) expert reports, (f) written discovery responses, and (g) any documents, things, copies and samples to the extent they include or reflect the receiving attorney's work product.

Within ninety (90) days after final termination of this Action, including all appeals, however, counsel for the Receiving Party shall (i) assemble and return to the Producing Party all other copies and samples of material designated Confidential; or, alternatively (ii) certify to the Producing Party in writing the destruction thereof. Accordingly, upon final termination of this Action, no one other than the outside counsel of record for each party shall retain any copies or samples of any material designated Confidential. For the avoidance of doubt, this paragraph applies equally to Confidential Information stored electronically, except that a party is not obligated to return or destroy Confidential Information that may be contained on electronic back-up tapes or other archival media, which should be treated in accordance with standard retention policies.

33. **Waiver or Termination of Order.** No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The termination of employment of any person with access to any Confidential Information shall not relieve such person from the obligation of maintaining the confidentiality of such information in accordance with this Protective Order.

34. **Modification of Order; Prior Agreements.** This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

35. **Section Captions.** The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

36. **Days.** All references to “days” in this Order shall be construed as calendar days, unless otherwise specifically indicated.

37. **Order Applicable Upon Filing with the Court.** Upon filing this Protective Order with the Court, the Parties agree to treat it as “So Ordered,” subject to any future modifications by agreement of the Parties or by the Court.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

STAMOULIS & WEINBLATT, LLP

/s/

Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
800 North West Street, Third Floor
Wilmington, DE 19801
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

*Attorneys for Defendant Aizant Drug Research
Solutions Pvt. Ltd.*

POTTER ANDERSON & CORROON LLP

/s/

Bindu A. Palapura (#5370)
Alan R. Silverstein (#5066)
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19801
(302) 984-6000
bpalapura@potteranderson.com
asilverstein@potteranderson.com

*Attorneys for Defendants Alembic
Pharmaceuticals, Inc. and Alembic
Pharmaceuticals, Ltd.*

MORRIS JAMES LLP

/s/

Kenneth L. Dorsney (#3726)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com

*Attorneys for Defendants Apotex Inc. and
Apotex Corp.*

BAYARD, P.A.

/s/

Stephen B. Brauerman (#4952)
600 King Street, Suite 400
Wilmington, DE 19801
(302) 655-5000
sbrauerman@bayardlaw.com

*Attorney for Defendants Dr. Reddy's
Laboratories, Ltd. and Dr. Reddy's
Laboratories, Inc.*

GREENBERG TRAURIG LLP

/s/

Benjamin J. Schladweiler (#4601)
The Nemours Building
1007 North Orange Street, Suite 1200
Wilmington, DE 19801
(302) 661-7000
schladweilerb@gtlaw.com

*Attorneys for Defendants Hetero USA, Inc.,
Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V
and Hetero Labs, Ltd.*

MORRIS JAMES LLP

/s/

Kenneth L. Dorsney (#3726)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com

*Attorneys for Defendants Aurobindo Pharma,
Ltd., Aurobindo Pharma USA, Inc., and Eugia
Pharma Specialties, Ltd.*

RICHARDS, LAYTON & FINGER, PA

/s/

Kelly E. Farnan (#4395)
Renee M. Mosley (#6442)
One Rodney Square, Suite 600
920 North King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
mosley@rlf.com

*Attorneys for Defendants Natco Pharma, Inc.,
Natco Pharma, Ltd., Cipla USA Inc. and
Cipla, Ltd.*

MORRIS JAMES LLP

/s/

Kenneth L. Dorsney (#3726)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com

Attorneys for Defendants Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc.

SHAW KELLER LLP

/s/

John W. Shaw (#3362)
Karen E. Keller (#4489)
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

Attorneys for Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd.

RICHARDS LAYTON & FINGER, P.A.

/s/

Kelly E. Farnan (#4395)
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com

Attorneys for Defendants Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc.

PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.

/s/

John C. Phillips Jr. (#110)
Megan C. Haney (#5016)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
mch@pgmhlaw.com

Attorneys for Defendants Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC and Cadila Healthcare Ltd.

POTTER ANDERSON & CORROON LLP

/s/

David E. Moore (#3983)
Stephanie E. O'Byrne (#4446)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
(302) 984-6000
dmoore@potteranderson.com
sobyrne@potteranderson.com

*Attorneys for Defendant Mylan
Pharmaceuticals Inc.*

SO ORDERED this _____ day of _____, 2019.

United States District Judge

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: PALBOCICLIB PATENT
LITIGATION

MDL No. 19-2912 (CFC)

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.

Plaintiffs,

V.

C.A. No. 19-743 (CFC) (Consolidated)

AIZANT DRUG RESEARCH SOLUTIONS
PVT. LTD.,

Defendant.

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.,

Plaintiffs,

V.

C.A. No. 19-1863 (CFC)

MYLAN PHARMACEUTICALS, INC.

Defendant

DECLARATION AND PROTECTIVE ORDER UNDERTAKING

I certify that I have received and carefully read the Stipulated Protective Order (“Order”) in the above-captioned Actions and that I fully understand the terms of the Order. I recognize that I am bound by the terms of the Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the United States District Court for the District of Delaware for any proceedings involving the enforcement of the Order. I declare under penalty of perjury under the laws of the United States of America that this Declaration and Confidentiality Undertaking is true and correct.

EXECUTED this ____ day of _____, _____.

Name

Signature

Present Employer or Other Business Affiliation

Business Address

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: PALBOCICLIB PATENT
LITIGATION

MDL No. 19-2912 (CFC)

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.

Plaintiffs,

V.

C.A. No. 19-743 (CFC) (Consolidated)

AIZANT DRUG RESEARCH SOLUTIONS
PVT. LTD.,

Defendant.

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.,

Plaintiffs,

V.

C.A. No. 19-1863 (CFC)

MYLAN PHARMACEUTICALS, INC.

Defendant

PLAINTIFFS' [PROPOSED] ORDER

AND NOW, this ____ day of December 2019, the Court having considered the parties' dispute regarding the parties' proposed Protective Order, IT IS HEREBY ORDERED that:

- 1) Defendants' Proposal to insert the following paragraph:

Subject to paragraph 7 [of the proposed protective order] and/or further order of the Court, Plaintiffs shall not disclose any material designated Confidential by a defendant in one of the Actions to a defendant in another Action absent the consent of the Producing Party

is REJECTED, and

2) Plaintiffs' Proposal to insert the following paragraph:

No party shall disclose any material designated Confidential by a Producing Party to another party without the consent of the Producing Party or by order of the Court, provided however, that any party shall be permitted to disclose in any trial, hearing, pleading, discovery response, deposition, or expert report that is properly designated as "Confidential" pursuant to this Order any material designated Confidential by any Producing Party. Notwithstanding anything in the Paragraph, no party shall disclose to a fact witness of one party, during his or her deposition, any material designated Confidential by another party.

is ADOPTED.

The parties shall file a [Proposed] Protective Order consistent with this Order within three business days of the date of this Order.

United States District Judge

EXHIBIT 3

LEAD,MEDIATION-MPT,PATENT

**U.S. District Court
District of Delaware (Wilmington)
CIVIL DOCKET FOR CASE #: 1:18-cv-00192-CFC**

Pharmacyclics LLC et al v. Fresenius Kabi USA, LLC et al

Assigned to: Judge Colm F. Connolly

Related Cases: [1:18-cv-00247-CFC](#)[1:18-cv-00275-CFC](#)[1:18-cv-00237-CFC](#)[1:18-cv-01543-CFC](#)[1:19-cv-00434-CFC](#)[1:18-cv-01778-CFC](#)[1:19-cv-00014-CFC](#)[1:19-cv-00143-CFC](#)

Cause: 35:271 Patent Infringement

Date Filed: 02/01/2018

Jury Demand: Defendant

Nature of Suit: 835 Patent - Abbreviated

New Drug Application(ANDA)

Jurisdiction: Federal Question

Plaintiff**Pharmacyclics LLC**represented by **Jack B. Blumenfeld**

Morris, Nichols, Arsht & Tunnell LLP

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899

(302) 658-9200

Email: jbbefiling@mnat.com**LEAD ATTORNEY****ATTORNEY TO BE NOTICED****Chanson Chang**Email: cchang@cov.com**PRO HAC VICE****ATTORNEY TO BE NOTICED****David S. Denuyl**Email: ddenuyl@cov.com**PRO HAC VICE****ATTORNEY TO BE NOTICED****Irena Royzman**Email: iroyzman@kramerlevin.com**PRO HAC VICE****ATTORNEY TO BE NOTICED****Jeremy A. Tigan**

Morris, Nichols, Arsht & Tunnell LLP

| | | |
|------------|--------------------|---|
| | | Set Hearings: A Discovery Conference is set for 10/17/2018 at 11:00 AM per request of counsel in Courtroom 4B before Judge Colm F. Connolly. Associated Cases: 1:18-cv-00192-CFC, 1:18-cv-00237-CFC, 1:18-cv-00247-CFC, 1:18-cv-00275-CFC(nmf) (Entered: 10/03/2018) |
| 10/03/2018 | | Pro Hac Vice Attorney John K. Hsu for Fresenius Kabi Oncology Limited, Fresenius Kabi USA, LLC added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (crb) (Entered: 10/03/2018) |
| 10/05/2018 | 44 | STIPULATION TO EXTEND TIME to EXTEND the deadline for Defendants' Initial Invalidity Contentions to 11/2/2018 - filed by Fresenius Kabi USA, LLC. (Farnan, Brian) (Entered: 10/05/2018) |
| 10/09/2018 | | SO ORDERED, re (71 in 1:18-cv-00275-CFC, 44 in 1:18-cv-00192-CFC, 55 in 1:18-cv-00237-CFC) STIPULATION TO EXTEND TIME to EXTEND the deadline for Defendants' Initial Invalidity Contentions to 11/2/2018 filed by Fresenius Kabi USA, LLC, (38 in 1:18-cv-00247-CFC) STIPULATION TO EXTEND TIME to Extend Deadline for Initial Invalidity Contentions to November 2, 2018 filed by Cipla Limited, Cipla USA Inc.. Signed by Judge Colm F. Connolly on 10/9/2018. Associated Cases: 1:18-cv-00192-CFC, 1:18-cv-00237-CFC, 1:18-cv-00247-CFC, 1:18-cv-00275-CFC(fms) (Entered: 10/09/2018) |
| 10/15/2018 | 45 | Letter to The Honorable Colm F. Connolly from Dominick T. Gattuso regarding Opening Discovery Dispute Letter. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Gattuso, Dominick) (Entered: 10/15/2018) |
| 10/16/2018 | 46 | Letter to The Honorable Colm F. Connolly from Jeremy A. Tigan regarding the proposed Protective Order - re (45 in 1:18-cv-00192-CFC, 39 in 1:18-cv-00247-CFC, 57 in 1:18-cv-00237-CFC, 73 in 1:18-cv-00275-CFC) Letter. (Attachments: # 1 Exhibits A-D)(Tigan, Jeremy) (Entered: 10/16/2018) |
| 10/17/2018 | | Minute Entry for proceedings held before Judge Colm F. Connolly - Discovery Conference held on 10/17/2018. (Court Reporter V. Gunning.) Associated Cases: 1:18-cv-00192-CFC, 1:18-cv-00237-CFC, 1:18-cv-00247-CFC, 1:18-cv-00275-CFC(nmf) (Entered: 10/17/2018) |
| 10/18/2018 | | ORAL ORDER, Having reviewed the parties' submissions and heard oral argument relating to two disputes over the otherwise agreed-upon protective order (PO) in Civil Actions 18-192-CFC, 18-237-CFC, 18-247-CFC, and 18-275-CFC, IT IS HEREBY ORDERED that Defendants proposal with respect to paragraphs 19 and 20 of the contemplated PO, which would prohibit Plaintiffs from disclosing confidential information (CI) produced to Plaintiffs in discovery by any one Defendant to the outside counsel and experts of any other Defendant without first obtaining the producing Defendants consent, is REJECTED for the reasons stated by the Court and made clear by the Courts questioning of the parties at oral argument on October 17, 2018. The Court further notes that its decision was informed by the following: (1) this action is one of four actions that have been effectively consolidated for pre-trial purposes with a single schedule (including a consolidated Markman hearing) and common discovery; (2) Plaintiffs have proposed a reasonable alternative to |

| | | |
|------------|--------------------|--|
| | | <p>Defendants' proposal that would limit the cross-disclosure of CI to Defendants' outside counsel and experts; (3) Defendants agree that their outside counsel are not competitive decision makers and are subject to an agreed-upon prosecution bar in the contemplated PO; (4) the deadline for the parties to identify their respective experts affords each Defendant sufficient time to seek Court intervention in the event a Defendant believes (i) an identified expert is a competitive decision maker or should be subject to the PO's prosecution bar, and/or (ii) good cause exists to prohibit the expert in question from having access to a Defendants CI; (5) Defendants' proposal would place an undue, unfair, and unnecessary burden on Plaintiffs; (6) Defendants' proposal would lead to significant disruptions in discovery, depositions, and court proceedings and would impose an undue burden on the Court; and (7) Defendants have not demonstrated that restrictions beyond Plaintiffs' proposed alternative are necessary to avoid the risk that a co-Defendant would use a producing Defendants' CI's to the competitive disadvantage of the producing Defendant. Ordered by Judge Colm F. Connolly on 10/18/2018. Associated Cases: 1:18-cv-00192-CFC, 1:18-cv-00237-CFC, 1:18-cv-00247-CFC, 1:18-cv-00275-CFC (nmf) (Entered: 10/18/2018)</p> |
| 10/22/2018 | 47 | NOTICE OF SERVICE of Plaintiffs' Responses to Defendants' First Set of Joint Interrogatories (Nos. 1-4) filed by Janssen Biotech, Inc., Pharmacyclics LLC, Janssen Biotech Inc..(Tigan, Jeremy) (Entered: 10/22/2018) |
| 10/26/2018 | 48 | PROPOSED ORDER // Protective Order by Janssen Biotech, Inc., Pharmacyclics LLC, Janssen Biotech Inc.. (Tigan, Jeremy) (Entered: 10/26/2018) |
| 10/29/2018 | 49 | NOTICE OF SERVICE of Plaintiffs' Objections and Responses to Defendants Fresenius Kabi USA LLC, Fresenius Kabi Oncology Limited, Zydus Worldwide DMCC, Cadila Healthcare Limited, Teva Pharmaceuticals USA, Inc., Sandoz Inc., and Lek Pharmaceuticals d.d.'s First Set of Requests for Production of Documents and Things (Nos. 1-99) filed by Janssen Biotech, Inc., Pharmacyclics LLC, Janssen Biotech Inc..(Tigan, Jeremy) (Entered: 10/29/2018) |
| 10/30/2018 | 50 | PROTECTIVE ORDER. Signed by Judge Colm F. Connolly on 10/29/2018. Associated Cases: 1:18-cv-00192-CFC, 1:18-cv-00237-CFC, 1:18-cv-00247-CFC, 1:18-cv-00275-CFC(fms) (Entered: 10/30/2018) |
| 11/02/2018 | 51 | NOTICE OF SERVICE of Defendants' Initial Invalidity Contentions filed by Fresenius Kabi Oncology Limited, Fresenius Kabi USA, LLC.(Farnan, Brian) (Entered: 11/02/2018) |
| 11/26/2018 | | ORAL ORDER: Whereas the Court directed the parties during the October 17, 2018 hearing to file a proposed scheduling order using the Court's form order and whereas the parties have not done so, it is hereby ORDERED that the parties shall file by no later than November 29, 2018 a proposed scheduling order using the Court's form order (revised as of November 14, 2018) that incorporates the dates and discovery limitations currently in effect. It is further ORDERED that for all purposes other than trial, these cases are to be treated as consolidated and all filings are to be made in Lead Case No. 18-192-CFC. Signed by Judge Colm F. Connolly on 11/26/2018. Associated Cases: 1:18-cv- |

EXHIBIT 4

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

(302) 658-9200

JEREMY A. TIGAN
(302) 351-9106
jtigan@mnat.com

The Honorable Colm F. Connolly
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

October 16, 2018

Re: Pharmacyclics LLC, et al. v. Fresenius Kabi USA, LLC, et al., C.A. 18-192-CFC (coord.)

Dear Judge Connolly:

Plaintiffs submit this response to Defendants' October 15, 2018 Letter regarding the proposed Protective Order (18-192, D.I. 45). For the reasons detailed below, Plaintiffs respectfully request that the Court deny Defendants' proposals to (1) largely prevent disclosure of any one Defendant's Confidential Information to outside counsel for another Defendant; and (2) allow Cipla's non-attorney IP personnel access to Plaintiffs' Confidential Information.

I. The Court should permit disclosure of Defendants' Confidential Information among outside counsel and Defendants' experts.

These four coordinated cases arise from seven companies filing Abbreviated New Drug Applications ("ANDAs") to market generic versions of Plaintiffs' IMBRUVICA[®] drug product. Because this action is effectively consolidated pre-trial—with a single schedule (including a consolidated *Markman* proceeding) and common discovery, 18-192, D.I. 32—Plaintiffs propose that the Protective Order allow for limited disclosure of each Defendant's Confidential Information to the other Defendants' outside counsel and independent experts. Ex. A ¶ 8. Defendants, by contrast, propose that Plaintiffs (and the Court) be prohibited from revealing the Confidential Information of one Defendant to *any* representative—including outside counsel—of any other Defendant, except in Court filings and Court Orders.

Defendants have not met their burden to show that the limited disclosure Plaintiffs have proposed should be prohibited.¹ *First*, Defendants' argument that Plaintiffs' proposal allows for purportedly improper and prejudicial use of one Defendant's documents against another is a red herring. Whether a document is admissible for a given purpose is an evidentiary issue assessed through mechanisms like formal exhibit lists and objections in Court—not one that should be decided by a blanket rule in a Protective Order. No party has agreed that all of its documents will be admissible for all purposes simply by signing onto a Protective Order. And Defendants' proposal also seemingly allows for such use of Defendants' documents in filings, and in discovery as long as Plaintiffs prepare redacted copies of their submissions.

Moreover, Defendants wrongly assert that their Confidential Information is categorically "not relevant to the validity of Plaintiffs' patents." 18-192, D.I. 45 at 1. The Federal Circuit routinely endorses reliance on this type of information as objective indicia of non-obviousness, including to show failure of others, long-felt but unmet need, copying, commercial success, and

¹ See Fed. R. Civ. P. 26(c); *In re Deutsche Bank Trust Co.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010) ("A party seeking a protective order carries the burden of showing good cause.").

industry praise.²

Second, Defendants fail to explain how sharing Confidential Information between *outside counsel and experts*, who are bound to follow the Protective Order, will lead to any concrete injury. Concern about inadvertent disclosure because Defendants are competitors cannot fairly support Defendants' argument, as this is a risk borne by *all* parties in this litigation. These same outside counsel represent companies seeking to compete directly with Plaintiffs in the market for IMBRUVICA, and will all be entrusted with Plaintiffs' Confidential Information, including highly sensitive technical materials relating to the IMBRUVICA's development and marketing. Indeed, despite contending that Defendants "face serious risks" under Plaintiffs' proposal, Defendants' own proposal would permit cross-disclosure through Court submissions and orders.³

As this District has recently recognized, permitting cross-disclosure of Defendants' information will aid in the orderly administration and handling of the case.⁴ Defendants' proposal would needlessly complicate joint conferences and court hearings; impede discovery; and hinder Plaintiffs' ability to communicate with the Court. As just one example, if the Court would like to understand the potential implications of a construction during the *Markman* hearing, and a term is relevant to a party's infringement positions, outside counsel for one or more of the parties would not be able to participate in that portion of the hearing. This would negatively impact the Court's ability to fully understand all parties' positions, and the excused parties' ability to participate.

Defendants' proposal also imposes unnecessary administrative burden on Plaintiffs and the Court. While Defendants may refer to Defendants' and Plaintiffs' Confidential Information collectively in discovery or in Court, Plaintiffs have no ability to do the same unless they first consult with Defendants—forcing Plaintiffs to reveal their work product impressions—or create numerous redacted copies of, for example, discovery papers or expert reports. This unfairness is underscored by the fact that Defendants removed a proposed provision requiring that Defendants "consider in good faith limited cross disclosure" "on an as-needed basis." *Compare* Ex. B ¶ 18 (Defendants' Aug. 21, 2018 Proposed Protective Order), *with* 18-192, D.I. 45, Ex. A ¶¶ 19–20. Under Defendants' proposal, counsel will also undoubtedly need to approach the Court before numerous depositions, hearings, or other proceedings for guidance or orders on confidentiality.

² *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1081–82 (Fed. Cir. 2012) (third-party's failure supported a finding of non-obviousness); *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) (commercial success of accused product relevant); *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053–54, 1056–57 (Fed. Cir. 2016) (en banc) (accused infringer's internal documents probative of industry praise, copying, and long-felt need).

³ At least several Defendants have previously agreed, in other cases, to this type of limited cross-disclosure. *See, e.g., Amgen Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 16-853-GMS, D.I. 108 at 1, ¶ 13 (D. Del. May 4, 2017) (Cipla, Sun, Zydus/Cadila permitted access f outside counsel).

⁴ *H. Lundbeck A/S et al. v. Apotex Inc., et al.*, No. 18-88-LPS, D.I. 106 (D. Del. Sept. 13, 2018) ("Defendants' proposal . . . risks imposing an undue burden on the Court (independent of the burden it imposes on Plaintiffs)."); *see also Shire, LLC v. CorePharma, LLC et al.*, 14-5694-JS, D.I. 62 at 28:21–28 (D.N.J. May 18, 2015) ("If the Court adopts Par's suggestion, the Court believes that it would create intractable management problems dealing with depositions, expert reports, the Markman hearing, et cetera.").

II. The Court should reject Cipla's request for access for non-attorney IP personnel.

Defendant Cipla has requested that non-attorney IP personnel be permitted access to Plaintiffs' Confidential Information. Because Cipla has indicated it intends to designate at least one qualified U.S. in-house attorney to receive such information, its request should be denied.⁵

The designation of a non-attorney employed by Cipla presents a significant risk to Plaintiffs' Confidential Information. This District has long recognized that limiting access to in-house counsel minimizes risk because, "[l]ike outside counsel, in-house counsel is bound by professional and ethical responsibilities and their conduct is subject to sanctions."⁶ Under Defendants' proposal, however, Plaintiffs would be sharing Confidential Information with an employee of a direct competitor, who is not subject to the same obligations. Notwithstanding any agreement to abide by the Protective Order, the "distinction matters" between attorneys and non-attorney personnel.⁷ "Non-attorneys are not officers of the court, are not bound by the same Code of Professional Responsibility, . . . are not subject to the same sanctions," and "cannot be disbarred or disciplined in the same way."⁸ Moreover, as courts have recognized, the risk of disclosure is heightened where—as here—the proposed designee is located abroad.⁹

The enhanced risk created by non-attorney access is unsurprising. Non-lawyer personnel often work in business or research capacities, making improper use of Confidential Information for non-litigation purposes—however unintentional—more likely. For example, Cipla's proposed representative, Ms. Priyanka Sane, is based in India and appears to be involved in "Patent Portfolio Management."¹⁰

Finally, Cipla's argument that this individual needs access to Plaintiffs' Confidential Information for effective case management fails to address several key issues.¹¹ Infringement will focus on Defendants' Confidential Information, not on Plaintiffs', and validity will largely focus on publicly available prior art. To the extent that Plaintiffs' Confidential Information is relevant to validity, Cipla has not explained why access for an in-house attorney—which Cipla concedes it has and will be adding to the Protective Order—would be inadequate.¹²

* * * * *

For these reasons, Plaintiffs respectfully request that the Court adopt Plaintiffs' proposed Protective Order (Ex. A).

⁵ *Cf. Cosmo Techs. Ltd. v. Lupin Ltd.*, C.A. No. 15-669-LPS, D.I. 56 (D. Del. July 28, 2016).

⁶ *Avery Dennison Corp. v. Minn. Mining & Mfg. Co.*, C.A. 01-125, 2001 WL 1339402, at *2 (D. Del. Oct. 26, 2001); *see U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984).

⁷ *Allergan, Inc. v. Teva Pharms. USA*, No. 2:15-1455-WCB, 2017 WL 772486, *4 (E.D. Tex. Feb. 28, 2017).

⁸ *Id.*; *see also Allergan, Inc. v. Taro Pharm. Indus. Ltd.*, No. 17-663-JFB-SRF, Tr. at 38:5–20 (D. Del. Nov. 6, 2017) (Ex. C).

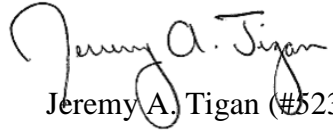
⁹ *Allergan v. Teva*, 2017 WL 772486, at *4.

¹⁰ Ex. D, P. Sane LinkedIn Biography.

¹¹ *See, e.g., Lundbeck*, No. 18-88-LPS, D.I. 106 (D. Del. Sept. 13, 2018); *see also Amgen*, C.A. No. 16-853-GMS, D.I. 108 at 7–8 (D. Del. May 4, 2017) (Cipla limits access to in-house counsel).

¹² Cipla's reference to Plaintiffs' agreement to permit non-attorney access for Zydus overlooks that Zydus is unable to designate any in-house attorneys, and is therefore differently situated.

Respectfully,

A handwritten signature in black ink, reading "Jeremy A. Tigan". The signature is fluid and cursive, with the first name "Jeremy" and last name "Tigan" clearly legible. The middle initial "A." is smaller and positioned between the first and last names.

Jeremy A. Tigan (#5239)

JAT/dam

Enclosures

cc: All Counsel of Record (by CM/ECF and email, w/encl.)

12294247

EXHIBIT 5



300 DELAWARE AVENUE • SUITE 200 • WILMINGTON, DELAWARE 19801
TEL: (302) 472.7300 • FAX: (302) 472.7320 • WWW.HEGH.LAW

Direct Dial: (302) 472-7311
Email: dgattuso@hegh.law

October 15, 2018

VIA ECF

The Honorable Colm F. Connolly
United States District Court
J. Caleb Boggs Federal Building
844 North King Street, Room 4124
Wilmington, DE 19801-3570

**Re: *Pharmcyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, C.A. 18-192-CFC
Pharmcyclics LLC et al. v. Shilpa Medicare Limited et al., C.A. 18-237-CFC
Pharmcyclics LLC et al. v. Cipla Limited et al., C.A. 18-247-CFC
Pharmcyclics LLC et al. v. Zydus Worldwide DMCC et al., C.A. 18-275-CFC**

Dear Judge Connolly:

We write on behalf of Defendants in the above-captioned cases regarding the following disputes that arose during negotiation of a Protective Order (“PO”): (1) Plaintiffs’ use and cross-disclosure of one Defendant’s proprietary information to other Defendants; and (2) access to designated information for a non-attorney responsible for supervising litigation on behalf of Cipla.

I. Plaintiffs Should Not Control Cross-Disclosure of Defendants’ Confidential Information

Defendants seek a reasonable and narrowly tailored provision that would prohibit Plaintiffs from generally disclosing information designated Confidential by one Defendant to another Defendant absent the first Defendant’s consent (*see* Paragraphs 19-20 of Exhibit A). Defendants’ proposal allows outside counsel of record for all Defendants to be served with any submission filed with the Court containing any of Defendants’ Confidential Information, and makes clear that any order issued by Your Honor that contains a Defendant’s Confidential Information may likewise be served on all outside counsel of record for Defendants. Plaintiffs continue to seek an unfettered ability to disclose one Defendants’ Confidential Information to another Defendants’ outside counsel and experts, without limitation.

A. Plaintiffs Do Not Need the Ability to Cross-Disclose Defendants’ Confidential Information

Plaintiffs have not articulated any basis, other than Plaintiffs’ own convenience, to disclose one Defendant’s Confidential Information to the other Defendants’ outside counsel or experts. But Defendants’ proposal ameliorates any alleged inconvenience to Plaintiffs by permitting disclosure of Confidential Information in Court submissions. Plaintiffs’ proposal, in contrast, far exceeds the bounds of convenience and would improperly permit Plaintiffs to use one Defendant’s Confidential Information against another Defendant.

Permitting Plaintiffs to do so would be unfair to the Defendants against which another Defendant’s Confidential Information may be used for several reasons. *First*, Defendants’ Confidential Information concerning their respective ANDA products is not relevant to the validity of Plaintiffs’ patents. *Second*, when assessing whether a particular Defendant’s ANDA product infringes, only that Defendant’s ANDA is relevant. *See Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) (“[T]he focus of the infringement inquiry under 35 U.S.C. § 271(e)(2)(A) is on the product that will be sold after the FDA’s approval of the ANDA”). Plaintiffs have acknowledged as

The Honorable Colm F. Connolly
October 15, 2018
Page 2

much by serving separate infringement contentions for each Defendant. *Third*, permitting Plaintiffs to use one Defendant's Confidential Information against another would prejudice Defendants because Defendants would have to address arguments based on evidence to which they had no previous access and which they have no way to independently investigate or corroborate. That in and of itself would be unfairly prejudicial and unwarranted, especially where Plaintiffs have provided no legitimate basis or need to disclose Defendants' Confidential Information except for Plaintiffs' own convenience.

B. Defendants Face Serious Risks Under Plaintiffs' Proposal

Defendants' proposal is necessary to protect each Defendant's Confidential Information from disclosure to its competitors. Plaintiffs do not dispute that details of Defendants' ANDA products are highly sensitive and confidential, particularly in these cases, which include patents directed to specific formulations and specific forms of the active pharmaceutical ingredients. Each Defendant—not Plaintiffs—is best positioned to gauge what, if any, of this information can safely be disclosed to others, even on an outside counsels' eyes only basis.¹

Each Defendant will potentially compete with all others when marketing generic ibrutinib. And, to the extent the outcome of the case, and thus market entry, is determined on an infringement issue, each Defendant will be severely prejudiced if its Confidential Information is directly or indirectly used against another Defendant. The FTC has long recognized that "firms that gain approval before rival generic firms are able to sell their product sooner, and face fewer initial competitors." *See* David Reiffen & Michael R. Ward, *GENERIC DRUG INDUSTRY DYNAMICS* 7 (Fed. Trade Comm., Working Paper No. 248, Feb. 2002), *available at* <https://www.ftc.gov/reports/generic-drug-industry-dynamics>.

It is not enough, as Plaintiffs contend, to limit the disclosure of Defendants' Confidential Information to the other Defendants' outside counsel and experts who may be called upon to advise their respective clients regarding ANDA and litigation strategy vis-à-vis the other Defendants. Courts recognize that the inadvertent use or disclosure of confidential business information is a significant risk that is best addressed through a clearly drafted PO designed to avoid the risk of inadvertent disclosure—precisely what Defendants' proposal accomplishes.

C. Defendants' Proposal Is Consistent With Numerous Prior Protective Orders

Litigants in patent cases have agreed to provisions similar to Defendants' proposal to protect Defendants' Confidential Information. In the handful of cases known to Defendants in which this issue

¹ During the meet and confer process, Plaintiffs stated that it would be unfair to allow Defendants to share information with each other, but preclude Plaintiffs from sharing Defendants' confidential information with other Defendants. This position is without merit. The Third Circuit has recognized that joint defense privilege protects "communications [that] are part of an on-going and joint effort to set up a common defense strategy." *Matter of Bevill, Bresler & Schulman Asset Mgmt.*, 805 F.2d 120, 126 (3d Cir. 1986); *see also In re Teleglobe Commc'ns Corp.*, 493 F.3d 345, 364-66 (3d Cir. 2007). Defendants' decision to share their own confidential information with each other in furtherance of a joint defense strategy in no way entitles Plaintiffs to disclose confidential information to other Defendants, even if only to outside counsel and experts. Moreover, Defendants' proposed protections against cross-disclosure will not prejudice Plaintiffs because Plaintiffs will have access to all of Defendants' Confidential Information.

The Honorable Colm F. Connolly
October 15, 2018
Page 3

has been disputed, courts have ruled in favor of defendants, stating in one such case that the court “sees efficiency in permitting each Defendant control over the disclosure of its confidential information to its direct competitors without unduly interfering with Plaintiffs ability to prosecute its case.” D.I. 77, *Supernus Pharms., Inc. v. Actavis, Inc.*, No. 2:14-06102, ¶ 2 (D.N.J. Sept. 23, 2015) (Ex. B).²

II. Cipla’s Non-Attorney Responsible for Managing This Litigation Should Have Access to Confidential Information Under the Protective Order

Cipla seeks a Stipulated PO that allows Cipla to designate a foreign, non-attorney to have access to Plaintiffs’ Confidential Information. Plaintiffs have refused to allow Cipla to designate such a person, despite allowing another defendant, Zydus, to do so.

As the parties seeking to restrict access, Plaintiffs bear the burden of establishing good cause to justify precluding Cipla’s non-attorney from accessing Confidential Information under the PO. *See Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, No. 15-691-LPS-CJB, 2016 WL 447794, at *1 n.1 (D. Del. Feb. 4, 2016). “Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984). Plaintiffs must make “a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.” *See Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986) (citation omitted). Plaintiffs cannot do so here.

Plaintiffs’ reason for refusing to allow access to Cipla’s in-house employee is that she is not an attorney. This does not establish “good cause” because it does not clearly define a serious injury and relies on a conclusory and stereotyped allegation of harm. Moreover, the following factors mitigate against Plaintiffs’ proposed restriction: (1) Cipla’s designee will be bound by the PO, subject to this Court’s jurisdiction for purposes of the PO, and will be supervised by attorneys bound by the PO, thereby providing more safeguards to Plaintiffs’ Confidential Information than with Zydus’s designee, who will lack attorney oversight; (2) Cipla’s non-attorney designee is not involved in competitive decision-making activities or FDA communications regarding ibrutinib; (3) Cipla’s intended designee has received confidential information under protective orders in this and other districts; and (4) Plaintiffs’ proposed restrictions will prejudice Cipla because Cipla’s non-attorney designee has the most intimate day-to-day knowledge of the ibrutinib project, while Cipla’s intended attorney designees have supervisory roles for this and other litigations and would be unable take on day-to-day management of this litigation. Finally, the proposed PO has a mechanism for Plaintiffs to make a particularized objection to Cipla’s specific non-attorney designee employee. That mechanism should be employed rather than categorically precluding designation of Cipla’s non-attorney designee.

* * *

For the foregoing reasons, Defendants respectfully request that the Court adopt Defendants’ proposed Protective Order.

² See also D.I. 67, *In re Fetzima*, No. 2:17-10230, ¶ 5 (D.N.J. May 21, 2018); D.I. 65, *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-cv-905, ¶ 3 (D. Del. July 20, 2017); D.I. 71, ¶ 16, *AstraZeneca LP v. Sigmapharm Labs., LLC*, 15-cv-1000 (D. Del. April 26, 2016).



The Honorable Colm F. Connolly
October 15, 2018
Page 4

Respectfully,

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)

Enclosures

cc: All Counsel of Record Via Electronic Mail

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN
BIOTECH, INC.,

Plaintiffs,

v.

FRESENIUS KABI USA, LLC and
FRESENIUS KABI ONCOLOGY
LIMITED,

Defendants.

C.A. No. 18-192 (CFC)

PHARMACYCLICS LLC, and JANSSEN
BIOTECH, INC.,

Plaintiffs,

v.

SHILPA MEDICARE LIMITED, SUN
PHARMA GLOBAL FZE and SUN
PHARMACEUTICAL INDUSTRIES LTD.,

Defendants.

C.A. No. 18-237 (CFC)

PHARMACYCLICS LLC and JANSSEN
BIOTECH, INC.,

Plaintiffs,

v.

CIPLA LIMITED and CIPLA USA INC.,

Defendants.

C.A. No. 18-247 (CFC)

| | | |
|-------------------------------|---|-----------------------|
| PHARMACYCLICS LLC and JANSSEN |) | |
| BIOTECH, INC., |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. 18-275 (CFC) |
| |) | |
| ZYDUS WORLDWIDE DMCC, CADILA |) | |
| HEALTHCARE LIMITED, TEVA |) | |
| PHARMACEUTICALS USA, INC., |) | |
| SANDOZ INC. and LEK |) | |
| PHARMACEUTICALS D.D., |) | |
| |) | |
| Defendants. |) | |
| |) | |

RULE 7.1.1 STATEMENT

Pursuant to District of Delaware Local Rule 7.1.1, Defendants in the above-captioned action hereby certify that they have engaged in reasonable efforts, including by electronic and telephonic means, to reach agreement with Plaintiffs on the matters concerning the parties' proposed Protective Order. The parties were unable to reach agreement.

OF COUNSEL:

Natalie C. Clayton
ALSTON & BIRD LP
90 Park Avenue, 15th Floor
New York, NY 10016-1387
(212) 210-9400
natalie.clayton@alston.com

Siraj M. Abhyankar
ALSTON & BIRD
One Atlantic Center
1201 West Peachtree Street, Suite 4900
Atlanta, GA 30309-3424
(404) 881-7000
shri.abhyankar@alston.com

Dated: October 15, 2018

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

*Attorneys for Sandoz Inc. and Lek
Pharmaceuticals d.d.*